

Applicants: Walter P. Carney, et al.  
U.S. Serial No.: 08/321,179  
Filed: October 11, 1994  
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**REMARKS**

Claims 1-18 are pending in the subject application. Claims 1 and 2 are under examination, and claims 3-18 have been withdrawn. Applicants have hereinabove canceled claims 2-18 without prejudice. Upon entry of this Amendment, claim 1 will be pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's objections and rejections made in the October 11, 2001 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

**Objection Under 37 C.F.R. §1.75(c)**

The Examiner objected to claim 2 under 37 C.F.R. §1.75(c) as allegedly of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Examiner states that the claim recites an inherent property of the claimed p100, which fails to further limit the structure or physical properties of the instantly claimed product.

In response to the Examiner's objection, but without conceding the correctness thereof, applicants point out that claim 2 has been canceled, rendering this objection moot.

**Rejection Under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 1 and 2 under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Examiner maintains as indefinite the language of claims 1 and 2, which recites the term "corresponds substantially".

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In response to the rejection of claim 2, applicants again point out that this claim has been canceled, rendering the rejection thereof moot.

In response to the rejection of claim 1, applicants respectfully traverse. In support of their traversal, applicants incorporate herein their remarks set forth in their April 1, 1996 Amendment covering this rejection, and make the following remarks to underscore their position.

The phrase "corresponds substantially" is a term of art that refers to providing for conservative additions, conservative deletions and conservative substitutions. In this context, the term "conservative" is known in the art as encompassing the replacement, addition or deletion of one or more amino acid residues of a polypeptide which do not alter the biochemical nature of the polypeptide and allows the peptide to retain substantially the same structural and biochemical features. As such, one skilled in the art would be able to determine whether a first polypeptide "corresponds substantially" with a second polypeptide differing from the first by known amino acid substitutions, additions and/or deletions.

Applicants note the Examiner's assertion that, in connection with the definition of "corresponds substantially" at the top of page 11 of the specification, the term "conservative" modifies "additions", but not "deletions" or "substitutions". In response, applicants disagree with the Examiner's position, and maintain that from the context of that phrase, i.e., "conservative additions, deletions and/or substitutions", it is clear that "conservative" modifies all three types of changes.

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In view of the above remarks, applicants maintain that claim 1 satisfies the requirements of 35 U.S.C. §112, second paragraph.

**Rejection Under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claims 1 and 2 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner asserted that the claims are "broadly drawn to any 'p100' which is a neu related protein having a molecular weight from about 97,000 daltons to about 115,000 daltons which corresponds substantially to the extracellular domain of the human neu gene product, and which is detectable in biological fluid". Thus, the Examiner maintains that the specification does not provide a written description of this invention.

In response to the rejection of claim 2, applicants again point out that this claim has been canceled, rendering the rejection thereof moot.

In response to the rejection of claim 1, applicants respectfully traverse the Examiner's rejection. Applicants maintain that based on the specification, applicants indeed had possession of the claimed invention. Specifically, applicants maintain that the claimed invention is exemplified at, inter alia, page 33, line 20 through page 38, line 21. It is further noted that applicants need not establish possession of every embodiment of the invention to satisfy the written description requirement.

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In view of the above remarks, applicants maintain that claim 1 satisfies the requirements of 35 U.S.C. §112, first paragraph.

**Rejection Under 35 U.S.C. §102(b)**

The Examiner rejected claims 1 and 2 under 35 U.S.C. §102(b) as allegedly anticipated by Bernards, et al. (PNAS, Vol. 84, pages 6854-6858, October 1987). Applicants point out that claim 2 has been canceled, rendering the rejection thereof moot.

In response to the Examiner's rejection of claim 1, applicants respectfully traverse.

Briefly, claim 1 provides a substantially purified p100 which is a human neu related protein having a molecular weight in the range from 97,000 daltons to about 115,000 daltons which corresponds substantially to the extracellular domain of the human neu gene product, said protein being detectable in a biological fluid.

To anticipate the invention of claim 1, Bernards would have to teach each and every element thereof.

It fails to do this. Rather, Bernards teaches a 100-kDa protein encoded by the rat-neu oncogene which, when a cDNA clone of the extracellular domain of said oncogene is transfected into a target cell line (CV-1), can be immunoprecipitated by an anti-rat neu (anti-p185) monoclonal antibody. Bernards therefore fails to teach each and every element of the rejected claim.

In view of the above remarks, applicants maintain that claim 1 satisfies the requirements of 35 U.S.C. §102(b).

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Rejections Under 35 U.S.C. §102(e)

The Examiner rejected claims 1 and 2 under 35 U.S.C. §102(e) as allegedly anticipated by Hudziak, et al. (U.S. Patent No. 6,015,567). The Examiner rejected claims 1 and 2 under 35 U.S.C. §102(e) as allegedly anticipated by Ring, et al. (U.S. Patent No. 6,054,561). Applicants point out that claim 2 has been canceled, rendering the rejections thereof moot.

In response to the Examiner's rejections, applicants respectfully traverse.

To anticipate the invention of claim 1, each of Hudziak and Ring would have to teach each and every element thereof.

They fail to do this.

Hudziak teaches a process for producing an extracellular portion of the HER2 molecule, which comprises ligating cDNA encoding a chain terminated mutant of the full-length wild-type HER2 protein into a suitable expression vector, transforming a suitable host (i.e., a bacterium or eukaryotic cell line) with the expression vector and culturing the host under conditions suitable for expression of the DNA and production of the protein.

Ring teaches novel polypeptides which are derived from antigen-binding sites of antibodies specific for cancer antigens, and have structure and function homologous to such antibody antigen-binding sites. Specifically, Ring teaches that one of the breast cancer-specific antibodies generated binds to an approximately 200 kDa protein identified as c-erbB-2.

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Neither Hudziak nor Ring teaches each and every element of the rejected claim.

In view of the above remarks, applicants maintain that claim 1 satisfies the requirements of 35 U.S.C. §102(e).

**Summary**

In view of the amendments and remarks made herein, applicants maintain that the claim pending in this application is in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee, other than the \$920.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents  
Washington, D.C. 20231.

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4/11/02

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